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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : James G. Barsoum et al.  
Application No. : 10/618,299 Confirmation No.: 6907  
Filed : July 11, 2003  
For : METHOD OF ENHANCING DELIVERY OF  
A THERAPEUTIC NUCLEIC ACID  
Examiner : Not Yet Assigned  
Group Art Unit : 1653

New York, New York  
February 24, 2004

Hon. Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR  
INFORMATION DISCLOSURE STATEMENT

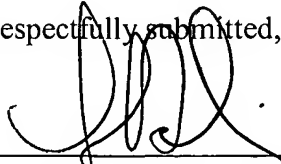
Sir:

Transmitted herewith is an Information Disclosure Statement (in duplicate) in the above-identified application, Form PTO-1449 (in duplicate) and documents cited therein. This Statement is submitted:

- ☐ within three months of the application filing date;  
☒ more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

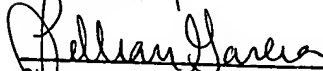


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Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants hereby make of record the references listed below. Copies of these references are enclosed. A completed Form PTO-1449 listing all of the documents is enclosed herewith in duplicate.

### United States Patents

| <u>Inventor</u> | <u>Patent No.</u> | <u>Issue Date</u> |
|-----------------|-------------------|-------------------|
| Higuchi et al.  | 3,710,795         | January 16, 1973  |
| Carter et al.   | 4,797,368         | January 10, 1989  |
| Kun et al.      | 5,262,564         | November 16, 1993 |
| Anderson et al. | 5,399,346         | March 21, 1995    |

### Foreign Patent Applications

| <u>Publication No.</u> | <u>Publication Date</u> | <u>Country</u> |
|------------------------|-------------------------|----------------|
| WO 99/10516            | March 4, 1999           | PCT (WIPO)     |
| WO 01/60377            | August 23, 2001         | PCT(WIPO)      |

### Articles

R. Alemany, et al., "Blood Clearance Rates of Adenovirus Type 5 in Mice," *Journal of General Virology*, 81(11):2605-9 (2000).

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- G. Schieder, et al., "Genomic DNA Transfer with a High-Capacity Adenovirus Vector Results in Improved *In Vivo* Gene Expression and Decreased Toxicity," *Nature Genetics*, 18(2):180-3 (1998).
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W. M. Tsui, et al., "Liver Changes in Reactive Haemophagocytic Syndrome," *Liver*, 12(6):363-7 (1992).

V. W. van Beusechem, et al., "Recombinant Adenovirus Vectors with Knobless Fibers for Targeted Gene Transfer," *Gene Therapy*, 7(22):1940-6 (2000).

N. van Rooijen, et al., "Transient Suppression of Macrophage Functions by Liposome-Encapsulated Drugs," *Trends in Biotechnology*, 15(5):178-185 (1997).

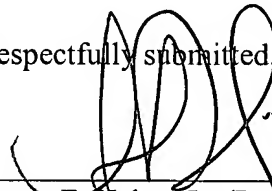
S. Wang, et al., "Effect of Clodronate on Macrophage Depletion and Adenoviral-Mediated Transgene Expression in Salivary Glands," *Journal of Oral Pathology and Medicine*, 28(4):145-51 (1999)

J. M. Wilson, et al., "Cystic Fibrosis. Vehicles for Gene Therapy." *Nature*, 365(6448):691-2 (1993).

G. Wolff, et al., "Enhancement of *In Vivo* Adenovirus-Mediated Gene Transfer and Expression by Prior Depletion of Tissue Macrophages in the Target Organ," *Journal of Virology*, 71(1):624-9 (1997).

Applicants respectfully request that the above-cited documents be (1) fully considered by the Examiner during the course of the examination of this application and (2) printed on any patent issuing from this application. Applicants also request that a copy of the enclosed Form PTO-1449, duly initialed by the Examiner, be forwarded to the undersigned with the next official communication.

Respectfully submitted,

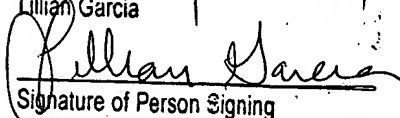


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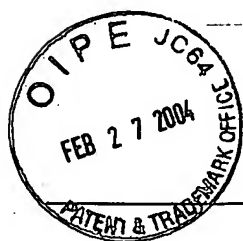
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Lillian Garcia



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FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.  
A123 CONSERIAL NO.  
10/618,299INFORMATION DISCLOSURE  
STATEMENT BY APPLICANTAPPLICANT  
James G. Barsoum et  
al.CONFIRMATION NO.  
6907

FILING DATE 07/11/03

GROUP 1653

## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT<br>NUMBER | DATE     | NAME            | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|---------------------|--------------------|----------|-----------------|-------|----------|-------------------------------|
|                     | 3,710,795          | 01/16/73 | Higuchi et al.  | 128   | 260      |                               |
|                     | 4,797,368          | 01/10/89 | Carter et al.   | 435   | 320      |                               |
|                     | 5,262,564          | 11/16/93 | Kun et al.      | 562   | 430      |                               |
|                     | 5,399,346          | 03/21/95 | Anderson et al. | 424   | 93.21    |                               |
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## FOREIGN PATENT DOCUMENTS


| EXAMINER<br>INITIAL | DOCUMENT NUMBER | DATE     | COUNTRY    | CLASS | SUBCLASS | TRANSLATION |    |
|---------------------|-----------------|----------|------------|-------|----------|-------------|----|
|                     |                 |          |            |       |          | YES         | NO |
|                     | WO 99/10516     | 03/04/99 | PCT (WIPO) | C12N  | 15/86    |             |    |
|                     | WO 01/60377     | 08/23/01 | PCT (WIPO) | A61K  | 31/66    |             |    |
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|  INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT |  | APPLICANT<br>James G. Barsoum et al. | CONFIRMATION NO.<br>6907 |
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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| EXAMINER<br>INITIAL |   |
|---------------------|---|
|                     | R. Alemany, et al., "Blood Clearance Rates of Adenovirus Type 5 in Mice," <i>Journal of General Virology</i> , 81(11):2605-9 (2000).  |
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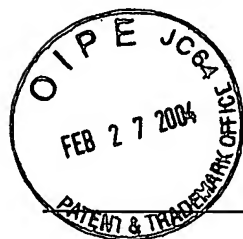
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